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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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<p>(21) International Application Number: PCT/HU87/00001 (22) International Filing Date: 8 January 1987 (08.01.87) (31) Priority Application Number: 79/86 (32) Priority Date: 8 January 1986 (08.01.86) (33) Priority Country: HU (71) Applicant: LICENCIA TALÁLMÁNYOKAT ÉRTÉKESÍTŐ ÉS INNOVÁCIÓS KÜLKERESKEDELMI VÁLLALAT [HU/HU]; P.O. Box 207, H-1368 Budapest (HU). (72) Inventor: POLGÁR, Péter ; István ut 119, H-4031 Debrecen (HU). (74) Agent: PATENTBUREAU DANUBIA; P.O.B. 198, H-1368 Budapest (HU).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent). Published With international search report.</p>
<p>(54) Title: ELECTRODE CATHETER FOR THE ABLATION OF THE HIS BUNDLE</p>		
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<p>(57) Abstract</p>		
<p>Electrode catheter (1) for the ablation of the His bundle which comprises a short hollow sleeve-like electrode (3) at an end of the catheter tube (2) with a central opening communicating with the interior of the catheter tube (2) through which a sucking force can be applied for positioning and fixing the electrode to the required wall portion of the heart. The electrode is used together with an outer electrode (4) for establishing an electrical shock that produces an AV block.</p>		

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ELECTRODE CATHETER FOR THE ABLATION OF THE HIS BUNDLE

The invention relates to an electrode catheter for the ablation of the His bundle which comprises a catheter tube with a frontal electrode and the tube has a frontal section defining an opening. A connector plug provides an electrical
5 connection for the frontal electrode.

A newer method for treating drug resistant paroxysmal supraventricular tachycardia employs the electrical destruction of the His bundle (i.e. AV junction). This method was described by Gallagher and his co-workers in 1982 (New England
10 Journal of Medicine 1982; 28 pp. 194-200).

The basic method is to deliver a DC shock to the His bundle through a conventional His electrode. The electro-coagulation thus leads to AV block. A disadvantage of the method is that the position of the electrode cannot be checked at the time
15 the DC shock is delivered. It may move and may cause injury to the myocardium elsewhere. A further drawback lies in the varying resistance of the contact between the electrode and the endocardium which may change from case to case and cannot be checked at all. For providing a sufficient destructive
20 effect, a high-energy electrical discharge should be established which can be accompanied by unwanted side effects.

An improved method for the ablation of the His bundle, the essence of which lies in the establishment of a suction effect by means of the electrode catheter used for providing the DC
25 shock for fixing the position of the electrode catheter on the His bundle has already been suggested (P. Polgár et al.: Closed-Chest Ablation of His Bundle: A new Technique Using Suction Electrode Catheter and DC Shock, In Steinbach, K. e.: Cardiac Pacing, pp. 883-890, Dr. D. Steinkopff Verlag, Darmstadt).

30 As was described in this paper, in addition to the electrode catheter provided with a central electrode for establishing the DJ block, a further electrode catheter with bipolar electrodes was used for the correct localization of the His bundle. The electrode catheters were introduced under an X-ray image

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intensifier, and the accurate intracardial positioning was made under control of ECG signals obtained by means of the separate bipolar electrodes.

Electrode catheters utilizing suction effects have been
5 widely used in medical practice. A known type of such electrodes is represented by the bipolar suction electrodes of the company VYGON (Aachen, Germany), e.g. the type 1172.06 used for recording monophasic action potentials. This type of electrode catheter comprises a small central opening at
10 its frontal end and a central electrode slightly extending out axially from the opening like the tip of a needle which is coupled to a coiled spring arranged in the interior of the frontal section of the catheter tube. The other electrode is arranged as a sleeve behind the short hollow frontal section
15 of the catheter tube of insulating material and this sleeve coaxially encircles the flexible central needle electrode. The application of such an electrode for establishing AV block is connected with a number of technical drawbacks. While it is preferable that the sucking force locks the electrode to
20 the His bundle, the position of the central needle electrode is secured only by the slight biasing force of the coiled spring. The thin needle electrode which has a diameter of only .16 mm will get heated by means of the large amount of energy used for coagulation and it can be destroyed earlier
25 than the target tissues.

There are other known types of electrode catheters provided with an opening for suction purposes that can be used preferably for sensing the internal pulmonary pressure. Such electrode catheters comprise a solid cylindrical frontal electrode
30 and a hollow rear electrode arranged about 15 mm behind the frontal electrode and the distance between the two electrodes is maintained by a short section of a catheter tube which is provided with a suction opening on its mantle surface (e.g. the type 1126.13 of the company VYGON). Such catheters cannot
35 provide the advantage of correct positioning referred to in above-cited paper when used for the ablation of the His bundle.

The object of the invention is to provide an improved elect-

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rode catheter for the ablation of the His bundle.

This object has been achieved by an electrode catheter which has a frontal electrode made as a hollow cylindrical sleeve that defines a central opening communicating with
5 the interior of the catheter tube and through which the sucking force is exerted, the axis of the frontal electrode forming the extension of the axis of the catheter tube, and the outer diameters of the frontal electrode and of the catheter tube being equal or nearly equal.

10 The frontal electrode of such an electrode catheter has an annular face which has a much larger contact surface than that offered by the needle electrode.

In a preferable embodiment the electrode catheter comprises a sleeve-like rear electrode arranged behind the rear end of
15 the frontal electrode at a distance between about 5 to 15 mm, and the frontal end of the catheter tube is coupled to a cylindrical shoulder of the rear electrode arranged concentrically around the catheter axis, and the rear electrode has a frontal shoulder similar to the rear one which is coupled
20 through a catheter tube section to the frontal electrode, and both of these electrodes are electrically connected to respective lead out wires extending in and insulated from the catheter tube, and these wires are coupled to respective connector plugs.

The so-obtained bipolar electrode renders the usage of a
25 separate bipolar electrode for the localization unnecessary and it is capable of delivering the bipolar ECG signals required for exact electrode positioning.

The application of the electrode catheter according to the invention is facilitated if a closing member is connected to
30 the rear end portion of the catheter tube and this member comprises a connection stub communicating with the interior of the catheter tube which is capable of providing a connection towards a pump, and the member comprises electrode wires interconnecting the lead out wires with the connector plugs.

35 In a preferable embodiment of the frontal electrode the thickness is decreasing towards the frontal end in an arced transition, whereby an annular face is provided which is narrower than the average wall thickness of the frontal elect-

rode.

The electrode catheter according to the invention can well be used for the ablation of the His bundle without the danger of unwanted side effects.

5 The invention will now be described in connection with a preferable embodiment thereof, in which reference will be made to the accompanying drawing. In the drawing:

10 Fig. 1 is a sketch illustrating the application of the electrode catheter according to the invention; and

Fig. 2 shows the enlarged elevation view of the frontal end section of the electrode catheter in half sectional view.

Fig. 1 shows a sketch of the application of electrode
15 catheter 1 made according to the invention. It is preferred if the electrode catheter is designed for a single use whereafter it should be disposed. The electrode catheter 1 comprises a catheter tube 2 which can have an F6 size according to the internationally accepted size standard and the catheter
20 can be 100 cm long.

A frontal electrode 3 is arranged in the frontal end of the electrode catheter 1 and a rear electrode 4 is located at a distance of about 10 mm behind the frontal electrode 3. A closing member 5 is coupled to the rear end of the catheter tube 2.
25 Member 5 is provided with a stub 6 to which the end of a suction pipe can be connected. Electrode wires 7 and 8 extend out from the member 5 with connector plugs 9 and 10 at their free ends.

In Fig. 2 the frontal section of the electrode catheter 1
30 is shown in an enlarged and partly sectional view. The frontal electrode 3 is a hollow sleeve which has a slightly arced frontal rim, and a thin lead-out wire 11 is connected to the interior of the sleeve by means of a soldered or any other unreleasable connection. In the embodiment shown in Fig. 2 the
35 rear electrode 4 is a short tube section provided with respective

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shoulders in the front and rear end portions. An extension tube 12 made of the same material as the catheter tube 2 connects the frontal shoulder of the rear electrode 4 to the frontal electrode 3. The interior of the rear electrode 4 is
5 connected to another lead-out wire 13 similar to the wire 11. The frontal end of the catheter tube 2 is tightly coupled to the rear shoulder of the rear electrode 4 and the so designed electrode catheter 1 has a hollow interior extending continuously throughout the full length thereof. In the closing
10 member 5 the two lead-out wires 11 and 13 are connected to the respective electrode wires 7 and 8.

Refer is made again to Fig. 1 which shows that the electrode catheter extends into the right heart after having been introduced by means of percutaneous puncture through the
15 femoral vein, and the frontal electrode 3 abuts the His bundle. This position can be adjusted under control of an electrocardiograph 15 coupled to the frontal and rear electrodes 3 and 4 and under fluoroscopic inspection. In the required position the tap valve of the closing member 5 is turned and the hollow
20 interior of the electrode catheter 1 is actively coupled to a suction pump 16 by which a depression of -13.6 kPa is established. As a result of the suction force the annular face of the frontal electrode 3 gets pulled to the His bundle. By maintaining the suction the frontal electrode 3 is affixed in
25 the adjusted location and position.

An outer electrode 17 is placed over the patient's left scapula, then the connector plug 9 coupled to the frontal electrode 3 and the electrode 17 are connected to respective terminals of a defibrillator 14 and by means of a synchronous
30 discharge of suitable energy, e.g. 50 Wsec, a DC shock is delivered. The resulting electro-coagulation provides a total AV block. Thereafter the suction is disrupted and physiologic saline is infused into the catheter to separate the frontal electrode 3 from the His bundle. The patient's heart is controlled with an external pacemaker via a previously introduced
35 right ventricular temporary pacing lead.

In case the total AV block persists up to 10 days, then a permanent pacemaker is implanted into the patient.

In the application of the electrode catheter 1 according to the invention, significant advantages are obtained over conventional technique by the accurate positioning of the frontal electrode 3 and by the better and safer electrical contact between the coagulating electrode and the His bundle. The combined effects of the suction forces and the definite abutment of the annular face of the frontal electrode 3 against the His bundle results in a contact with small transitional resistance, whereby a smaller energy is sufficient for providing the required AV block.

The existence of these advantages has been fully confirmed by the numerous experiments made up to the present, and it has turned out that the ablation made by means of the electrode catheter 1 according to the invention has been safer also from the point of view of the patient. Complication has not been observed in any of the experiments.

Claims:

1. An electrode catheter for the ablation of the His bundle by application of a DC shock, comprising a catheter tube, a frontal electrode attached to a frontal end of the catheter tube formed as a hollow sleeve defining a frontal opening
5 communicating with the interior of the catheter tube, a first lead out wire capable of conducting an amount of energy during application of said DC shock sufficient to induce the desired ablation, said first lead-out wire being electrically connected to the frontal electrode and extending longitudinally inside
10 the catheter tube and being releasably connectable to a discharge means supplying said energy, the other end of the catheter tube being operatively connected to a pump means for establishing a depression through said frontal opening for holding said frontal electrode against a predetermined portion of the intracardial wall
15 at least during the application of said shock.

2. The electrode catheter as claimed in claim 1, wherein said frontal electrode has an outer diameter substantially equal to the outer diameter of the catheter tube.

3. The electrode catheter as claimed in claim 1, further
20 comprising a rear electrode made as a short hollow tube and arranged coaxially behind said frontal electrode at a distance between about 5 to 15 mm therefrom, with a rear part connected to said frontal end of said catheter tube, a tube section of insulating material interconnecting said frontal electrode with
25 a frontal part of said rear electrode, said frontal electrode being attached to said frontal end of said catheter tube by means of said tube section and said rear electrode, and a second lead out wire electrically connected to the interior of said rear electrode and extending longitudinally in the catheter tube
30 beside said first lead out wire.

4. The electrode catheter as claimed in claim 3, further comprising a closing member attached to the rear end of the

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catheter tube, wherein said closing member includes a means for releasably closing or opening the communication path towards said connection to the discharge means, said first and second lead out wires being connected to respective
5 electrode wires extending out from said closing member.

5. The electrode catheter as claimed in claim 4, further comprising connector plugs at the end of said electrode wires.

6. The electrode catheter as claimed in claim 1, wherein said frontal electrode has a constant inner diameter and
10 the outer contour thereof is narrowing towards the frontal end in an arced profile.

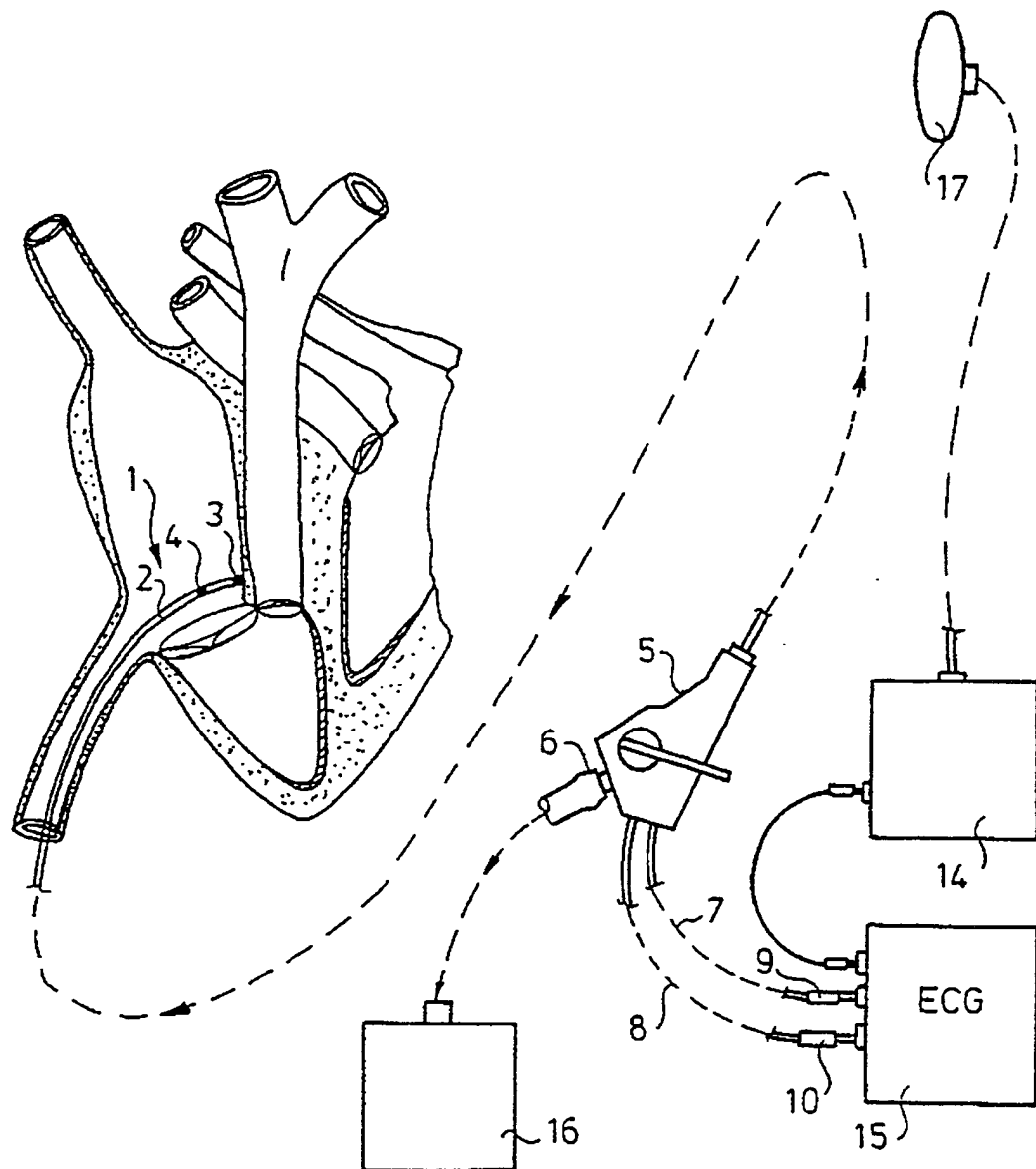


Fig.1

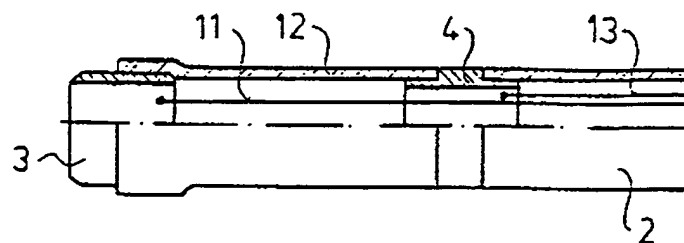


Fig.2

INTERNATIONAL SEARCH REPORT

International Application No PCT/HU 87/00001

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) * According to International Patent Classification (IPC) or to both National Classification and IPC IPC ⁴ : A 61 N 1/05, A 61 B 5/04						
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 30%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px;">Int.Cl.⁴</td> <td style="padding: 5px;">A 61 N; A 61 B; A 61 M</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched⁸</div>			Classification System	Classification Symbols	Int.Cl. ⁴	A 61 N; A 61 B; A 61 M
Classification System	Classification Symbols					
Int.Cl. ⁴	A 61 N; A 61 B; A 61 M					
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹						
Category ⁹	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³				
Y	Soviet Inventions Illustrated, section P,Q, week 85/37, 23 October 1985 (23.10.85) Derwent Publications LTD. London, P34, SU-1140 792 (KAUN).	(1) (2,5,6)				
Y	Soviet Inventions Illustrated, section P,Q, week 84/39, 07 November 1984 (07.11.84) Derwent Publications LTD. London, P34, SU-1069 829 (KAUN MED).	(1)				
A	Soviet Inventions Illustrated, section P,Q, week 85/10, 17 April 1985 (17.04.85) Derwent Publications LTD. London, P34, SU-1107 875 (KIEV DOCTOR).	(1)				
A	FR, A1, 2 560 052 (BENHAIM) 30 August 1985 (30.08.85), see abstract; page 4, line 14 - page 5, line 12; page 6, lines 4-12; fig. 1,2,4.	(1,3,5)				
A	DD, A, 98 608 (KABUS) 05 July 1973 (05.07.73), see column 3, lines 10-35; fig. 1,2.	(1)				
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Δ" document member of the same patent family</p> </div> </div>						
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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	GB, A, 2 154 884 (BRUNSWICK) 18 September 1985 (18.09.85), see abstract; fig. 3.	(1,3)
A	US, A, 4 090 518 (ELAM) 23 May 1978 (23.05.78), see abstract; fig. 2,8-11.	(1,4,5)

Anhang zum internationalen Recherchenbericht über die internationale Patentanmeldung Nr.

Annex to the International Search Report on International Patent Application No. PCT/HU 87/00001

Annex au rapport de recherche internationale relatif à la demande de brevet international n°.

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Im Recherchenbericht angeführtes Patent- dokument Patent document cited in search report Document de brevet cité dans le rapport de recherche	Datum der Veröffentlichung Publication date Date de publication	Mitglied(er) der Patentfamilie Patent family member(s) Membre(s) de la famille de brevets	Datum der Veröffentlichung Publication date Date de publication
SU-A -1 140 792	23/10/1985	None	
SU-A -1 069 829	07/11/1984	None	
SU-A -1 107 875	17/04/1985	None	
FR-A1-2 560 052	30/08/1985	None	
DD-A - 98 608	05/07/1973	DE-U -7 309 741	27/09/1973
GB-A -2 154 884	18/09/1985	DE-A1-3 506 653	10/10/1985
		US-A -4 574 807	11/03/1986
US-A -4 090 518	23/05/1978	None	